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Little is known about the influence of physician characteristics on breast cancer care, or the interaction of physician and patient characteristics on this care. The primary aim of the study is to investigate how physician gender influences care for breast cancer patients. Secondly, we wish to examine the independent and joint influences of physician characteristics including geographic region, race, experience, and specialty, and patient characteristics including race, age, socioeconomic status, comorbidities, and mobility on breast cancer care.

We are conducting a fractional factorial experiment where two medical scenarios are produced for videotape of a woman presenting breast cancer care. Sixteen versions of each videotape maintain the same clinical information while varying only those patient features as part of the experimental design. Pairs of female and male physicians matched on specialty, race, and experience are recruited from three geographic areas to view one version of each videotape and state their management recommendations. Analyses will compare management practices of female and male physicians independent of other physician and patient characteristics, as well as the interactive influence of these factors on patient care. The results of this study will define variation in breast cancer care and can lead to new strategies to target specific groups of physicians to improve breast cancer care.

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5.0 INTRODUCTION

5.1 Background

Extensive literature indicates that patient minority race, low socioeconomic status and increased age adversely influence outcomes for breast cancer, including stage of diagnosis (Mueller, 1978; Satariano, 1986; Wells, 1992; Swanson et al, 1993; Richardson, 1992) extensiveness of evaluation and treatment (Greenfield, 1987; Samet, 1986; Goodwin et al, 1986; Chu et al, 1987), and survival (Ayanian, 1993; Karajalainen, 1990; Kimmick, 1991; Bergman, 1992; Bassett, 1991). The extent to which theses differences are attributable to access to the medical system, patient behavior within the medical system, or physician decision making once the patient reaches medical care has been difficult to determine. Previous work often has had difficulty in disentangling the effects of delay in presentation of disease to factors of care once a patient has presented with disease as the reason for differences in outcomes.

Previous research has shown that sociocultural factors affect diagnosis, forms of treatment, prescribing and referral patterns and prognosis (Hartzema and Christensen, 1983; Mushlin and Appel, 1976; Van Horne, 1975; Eisenberg, 1979; Benson, 1983; Stimson, 1976; Rosenblatt and Moscovice, 1984). A patient's age influences physician perceptions of signs of illness versus concomitants of normal aging (Haug, Ory, 1987), and affects diagnostic evaluation and treatment for breast cancer. Compared with younger women, older women do not receive diagnostic evaluations which are as complete or treatment as aggressive. Chu et al (1987) found that women over age 65 were less likely to receive a complete diagnostic evaluation including biopsy prior to definitive therapy. Silliman et al (1989) found that women over age 75 were less likely to receive an appropriate diagnostic evaluation that included mammography and breast biopsy. When controlling for comorbid conditions, Greenfield et al (1987) found no difference in diagnostic evaluation by age. These and other investigators (Steinfeld 1989) found that women over age 75 were less likely to undergo lymph node dissection than younger women.

Patient age also influences treatment for breast cancer. Using New Mexico tumor registry data, Samet et al (1986) found that the likelihood of receiving definitive treatment for local and regional stage breast cancer decreased with increasing age. Chu (1987) and Silliman (1989) found that older women were less likely to receive radiation or chemotherapy than younger women. Data from the NCI SEER program indicate that older women were less likely to have surgery, but if they did, it was less extensive than in younger women. For example, the percentage of women who had axillary node dissection declined from 18% for the youngest women to 4.2% for the oldest women (Yancik et al, 1989). Greenfield et al (1987) found that age influenced the overall appropriateness of care for breast cancer for all women, and that this was most prominent for women with stage III or IV disease.

Other studies have suggested that differences in treatment may be due to the presence of comorbid conditions (Samet et al, 1986) which are unrelated to the cancer. Subsequent work has not substantiated these findings. Greenfield et al (1987) examined difference in treatment of breast cancer by patient age, controlling for comorbidity. Comorbidity could not explain all of the age related variability of treatment. Other demographic factors (i.e., race, social class, insurance, and hospital type) have been studied as determinants of breast cancer diagnosis, treatment, and survival. Ayanian et al (1993) found that compared to privately insured patients, those with Medicaid or no insurance had lower survival rates after controlling for stage of presenting disease, and suggested that is because they receive less optimal care. Using the New York state tumor registry, Mandelblatt et al (1991) reported that black race, lower social class and use of public hospitals were independently associated with later stage diagnosis. McWhorter and Mayer (1987) examined race, age, and disease stage as predictors of initial treatment and survival using the SEER data. There was an interaction between age and race, with older black women receiving the least treatment. Controlling for type of initial treatment, women 60 years of age and older had a lower risk of death than those under 50 years; black women continued to have higher death rates than whites. These data suggest that the effect of age on type of treatment received may be modified by race and other demographic factors.

The existing studies to understand survival differences by sociodemographic factors deal with differences in the patient's ability to access the health care system, or differences in patient's ability to complete treatment. Few studies has looked at how physician decision-making influences the care for breast cancer offered to patients once in the health care system, and whether part of the variation in outcomes seen in women by sociodemographic factors is due to physician behavior. One reason that the role of physicians' decision making in variation has not been studied has been the difficulty in controlling adequately the variability in the patient's clinical status as well as their sociodemographic status to see the independent effect of the decision making process. Observational studies lack the ability to completely control for differences in the clinical presentation of a patient, or to independently assess the effect of race from socioeconomic status, and of age from comorbidities involving life expectancy or mobility.

Less is known on how physician characteristics influence the decision-making process. Several physician characteristics alone, and in conjunction with patient variables, appear to influence physicians' diagnostic and treatment decisions. One factor that has recently received attention is the effect of physician gender on patient care and in particular, care to women (Rosenblatt and Moscovice, 1994; West, 1984; Bernstein and Kane, 1981). Studies have shown that women physicians spend on average more time with patients than do male physicians (Roter et al 1991; Hall et al 1990). Women physicians ask more questions, provide more information and counseling, and provide more choices and guidance rather than dictating intervention than their male counterparts (Roter 1993). This approach to the patient-physician interaction has been shown to be associated with women physicians identifying more medical and psychosocial problems than male physicians in both male and female patients (Bensing et al 1993). Recent work has shown that women physicians provide more

screening and prevention services, including mammography and clinical breast examination than their male counterparts (Lurie 1993; Frank and Clancy 1993). Only one study has investigated the effect of physicians' sex on breast cancer care. Belanger and colleagues (1991) attempted to sample equal proportions of men and women practicing in each specialty group, although they were unable to identify sufficient numbers of women, especially in surgery and radiation oncology. They found few treatment differences by physicians' gender, although women tended to offer their patients a choice of therapy more often than their male colleagues.

While the literature on clinical decisions and physician characteristics is limited, work specifically on physicians treating breast cancer is even sparser. Belanger also looked at physician age, and specialty factors which may influence treatment decisions. Younger physicians tended to select more aggressive treatment, such as chemotherapy, than their older colleagues and were more likely to recommend clinical trials. Physicians tended to recommend treatment within their own specialty; that is, surgeons were more likely to recommend surgery and radiation oncologists recommended radiation therapy. Other factors that may influence physician behavior in delivering appropriate care include both their knowledge and their attitudes. Physicians may be treating the elderly differently because they are unaware of recent findings negating the scientific basis for such practices. Previous studies have documented the difficulty in disseminating information to providers and changing their behavior. These efforts have shown that substantial delays occur between research being published and providers being aware of findings (Stross and Harlan, 1979), that it is difficult to transfer practice guidelines into clinical practice (Lomas and Haynes, 1988), and that information dissemination alone may not be sufficient to change behavior (Lomas et al, 1989). One study investigating the use of clinical trials found that in issues where consensus is low, such as management of Stage IIA disease, variability among physicians was high, although the certainty each physician felt about their own recommendations was also very high (Deber and Thompsom 1990), and that these attitudes may provide the most profound differences in care when consensus for treatment is not established.

Physician experience has been associated with differences in test ordering (Manu and Schwartz, 1983; Hemminki, 1974; Stolley et al, 1972) and prescriptions (Hemminki, 1974; Benson, 1983; Joyce et al; 1967). Physician race (McLaughlin and Balch, 1980; Rocheleu, 1978), and mode of payment (Schroeder and Showstack, 1978; Renaud et al, 1980; Roemer and Shonick, 1981) also have been correlated with different treatment decisions. Data on how race of physician or racial congruity/disparity in the physician/patient interaction influences decision making has not been investigated. Data on racial differences in care received has been documented, the extent to which this is a proxy for other sociodemographic characteristics has not been fully evaluated, especially the ability to assess if this is due to economic differences.

Physician geographic location has been documented to be a major source of treatment variation. Studies have included a number of areas in health care delivery (Wennberg 1973) including low back pain and cervical spine surgery (Barron 1992; Einstadter et al 1993),

prostatectomy (Lu-Yao et al 1993), endarterectomy (Winslow 1988) and other common medical and surgical procedures (McPherson and Wennberg 1982; Chassin and Brook 1986; Park 1986). It is unknown what factors are associated with this variability, and to what extent this reflects inappropriate care or regional difference in physician beliefs in those clinical areas where definitive trials have not been undertaken (Roos 1984; Chassin 1987; Chassin 1993).

Two recent articles have looked at treatment variation in breast cancer. Using the SEER data from 1983 through 1986, Farrow et al (1992) found four-fold differences in use of breast conserving surgery (i.e., not mastectomy) across the nine geographic regions. Age and race of patients were not significant covariates in use of breast conserving surgery, although older and black women were offered radiation therapy as adjunctive therapy less often. Another study using HCFA administrative data for 1986 found four to five-fold differences by state in use of breast-conserving surgery for women ages 65 to 79. In this analysis, black race was associated with lower use of breast conserving surgery, as was smaller metropolitan areas, the absence of radiation therapy in the hospital of surgery, and hospital size, (Nattinger et al 1992).

5.2 Previous Studies

The current study builds upon the recently completed investigation of physicians decisions making around breast cancer (AG11352). The recently completed studied developed two professional videotape scenarios of a woman presenting with a breast mass, or with Stage IIA breast cancer. Physicians were recruited as subjects to view one version of each scenario and state their management recommendations.

5.3 Experimental Design

A fractional factorial design was employed, permitting simultaneous evaluation of six dichotomous patient characteristics (age, race, socioeconomic status, comorbidity, assertiveness, frailty) (Cochran and Cox, 1957; Kirk, 1993). Two medical scenarios were professionally produced for videotape of elderly women requiring breast cancer evaluation and care. For each scenario, 32 versions of each videotape were produced that maintained the same clinical information while experimentally varying only those patient features as part of the experimental design. The characteristics were balanced so that each combination of one or two characteristics appears exactly half the time with each other characteristic.

Two scenarios were developed each depicting a doctor/patient encounter. The first scenario depicted the patient presenting for the evaluation of a possible breast cancer. The case was designed to maximize clinical uncertainty, with an equivocal clinical examination, and a negative mammogram. This allowed for the greatest range of appropriate management options.

In the second scenario, the patient presents for a second opinion after a biopsy-proven 0.8 cm infiltrating ductal carcinoma, with clean margins on the biopsy specimen, and equivocal hormone receptors. If the physician chooses to obtain staging information, he will discover that 2 of 29 tested nodes are positive for tumor, all metastatic evaluation is negative. Thus the patient has stage IIA disease, an area with lack of consensus on the need for adjuvant therapy, and whether chemotherapy or tamoxifen is the most appropriate (McFall, 1993).

The scripts were based on cases provided by two experienced clinicians and were reviewed for authenticity by a panel of practicing physicians. The dialogues were enacted by professional actors and videotaped professionally. Strict quality control procedures were followed during videotaping to ensure identical scripts. One actor played the character of the doctor. The verbal and non verbal behaviors of the patient-actresses was standardized.

The six dichotomous patient characteristics experimentally manipulated in the videotapes were age, race, socioeconomic status, physical mobility, assertiveness, and comorbidities. Patients were portrayed by eight actresses, each one selected for a combination of age, race and SES. Age of either 65 or 80 years was portrayed by actresses of the corresponding age and listed in the character synopsis at the beginning of the videotape. Likewise race was portrayed by actresses from those racial groups. Socioeconomic status was expressed visually in style of dress, verbally in minor grammatically alterations to the script, and by insurance coverage of either Medicaid or Medex supplement to Medicare listed in text form at the beginning of the tape. Comorbidity was the presence of no other medical problems or hypertension and diabetes, displayed as text at the beginning of the video and also by alternate variants in dialogue. Physical mobility was enacted with either no impairment or frailty defined as severe osteoarthritis of the knees in the patient synopsis, and portrayed the actress using a walker. Assertiveness was portrayed as a tag at the end of each videotape, where the patient specifically states her desire to be informed about test results and to be involved in the decision-making process, and that she wishes to take an aggressive approach towards treatment.

Subjects were selected from practicing physicians in Massachusetts in gynecology or surgery who either had performed both an open breast biopsy and mastectomy in the past five years, or medical and radiation oncologists who had cared for women with breast cancer in the past five years. A balanced sample of physicians who perform surgery and those who did not was obtained, as well as a balanced sample of physicians with fewer or greater than 15 years in practice since completing training. Excluded were physicians who trained outside the United States. There were insufficient physicians of color or women physicians to study these characteristics, therefore, to prevent confounding based on physician race and gender, we selected only white male physicians, the only group from which we could reliably obtain a sample of such specialists in our geographic area. Physicians were selected randomly from listings of licensed physicians from the Massachusetts Board of Registration and Business Mailers, Inc. Once selected, physicians were sent an introductory letter, followed by telephone recruitment call. Physicians were paid $100 to participate.

Semi-structured interviews were conducted by two trained interviewers. To enhance external validity, that is, whether physicians' responses to the videotape reflected their behavior in everyday practice, we attempted to recreate as much as possible the an actual office encounter. All interviews occurred in the physicians offices during their regular office hours. For each scenario, physicians were invited to state what further diagnostic evaluation they would order. Upon requesting specific diagnostic tests, they were then provided with the "results" in the form of a simulated laboratory report. Physicians were allowed to order testing in sequential fashion, that is, obtaining further studies based on the results of the initial tests requested, to simulate ordering behavior in real practice. The physician was asked what recommendation for evaluation and follow up he would make, and whether and the kinds of alternative information he would offer to the patient.

5.4 Results

5.4.1 *Patient Characteristics*

Case 1: A Possible Breast Mass

Forty-one percent of physicians felt breast cancer to be the most likely diagnosis, and 86% of physicians considered breast cancer as one of their three likely diagnoses. The mean physician estimate of the likelihood that the mass was due to cancer was 46% (95% confidence interval 34% - 58%).

Patient factors did influence the probability estimate of breast cancer. Physicians were more likely to rank breast cancer as the most likely diagnosis for older patients, with 45% of 80 year old versus 23% of 65 year olds ($p < .009$) given breast cancer as the most likely diagnosis. A trend was present for women of lower SES being more likely (42%) than higher SES (26%, $p < .07$) to be given breast cancer as the most likely diagnosis.

Although the probability estimates for breast cancer varied by patient age and SES, this did not result in changes in proposed management. Sixty-five percent planned some type of tissue biopsy (15% with a fine needle aspiration biopsy, and 50% with an open biopsy), and 35% intended to follow the patient over time with serial examinations and/or mammography. These decisions plans did not vary by patient age, SES, race, frailty, or comorbidity.

Case 2: Known Breast Cancer

Considerable variation in physicians' preferred management plan was noted for the second case of the woman with the Stage IIA breast carcinoma. Axillary node dissection to provide nodal staging was a preferred management option for 58% of physicians. Metastatic evaluation was not performed by 13% physicians, was limited to complete blood count, liver function tests and chest radiograph in 29%, and was more extensive by 58% of physicians, with 52% ordering bone scans. Eighty percent recommended breast conserving

surgery for this patient. Seventy-six percent recommended full primary therapy, that is, either breast conserving surgery and radiation (56%), or mastectomy (20%). Adjuvant therapy of some form was recommended by 65%. with 45% recommending tamoxifen, and 24% recommending chemotherapy. When mastectomy was recommended, only 28% recommended or offered reconstruction.

Patient age was associated with three of the dependent measures. Seventy-three percent of physicians recommended axillary node dissection when the patient was 65 years old, as opposed to only 42% when the patient was 80 years old (O.R. = 4.4 (C.I. 2.0 - 9.8)). Forty percent of 65 year olds were offered chemotherapy, compared with 8% who were 80 years old (O.R. = 9.9 (3.3 - 29.8)). The use of reconstruction following surgery also varied by age, with 38% of 65 year olds versus 18% of 80 year olds offered reconstruction (O.R. = 3.3 (1.3 - 8.6)). The use of full primary therapy, either mastectomy or lumpectomy with radiation therapy did not vary by patient age, and specifically there were no differences in the use of radiation therapy after breast conserving surgery. The use of tamoxifen also did not vary by age.

Patient race did influence the recommendation for metastatic evaluation, and the use of adjuvant therapy. Fifty-eight percent of black women were offered metastatic evaluation beyond radiograph of the chest and liver chemistries and blood counts, compared with 42% of white women (O.R. = 1.7 (1.1-2.7)). With regard to adjuvant therapy, the recommendation of either chemotherapy or tamoxifen was greater for black than white women (O.R. 2.6 (1.2-5.7)). The recommendation for tamoxifen was given to 54% of black women versus 36% of white women (O.R. 2.2 (1.1-4.7)), the use of chemotherapy favored black women over white women but was not significantly different (28% for black women, 20% of white women, O.R. 1.7 (.7 - 4.5). Patient race did not influence the type of surgery offered, or the use of axillary dissection or radiation therapy.

Socioeconomic status was associated with adjuvant therapy; 73% of higher SES women were offered either chemotherapy or tamoxifen, compared with 53% of lower SES women (O.R. 2.5 (13.-5.0)). The use of tamoxifen or chemotherapy individually did not reach statistical significance. Socioeconomic status was not a predictor of differences in staging evaluation or primary therapy.

Frail women were offered chemotherapy less frequently, (17% of the time), compared with 31% of agile women (O.R. 2.7 (1.1-7.0)). Frailty did not influence staging evaluation or recommendations for surgery or radiation therapy. The presence of comorbidities resulted in 69% receiving recommendation for axillary node dissection, compared with 46% of women without comorbidities (O.R. 2.9 (1.3-6.5)). Comorbidity was not associated with any other treatment recommendations. Patient assertiveness was not associated with any of the primary outcomes.

5.4.2 *Physician Characteristics*

Physician specialty did influence the evaluation of a potential breast cancer and the treatment of a known breast cancer. Surgeons were less likely than non-surgeons to think that breast cancer was the principal diagnosis (25% vs 42%). This difference persisted in a multiple logistic model considering all independent variables (OR = O.4, 95% CI = 0.2 - 0.9). Surgeons were also less likely to obtain a tissue diagnosis than non-surgeons (70% vs 89%). In a multiple logistic model controlling for the estimated probability of breast cancer, surgeons remained less likely than non-surgeons to obtain tissue for diagnostic purposes (OR = 0.3, 95% CI = 0.1 - 0.9). However, in the second scenario, among the 103 physicians who recommended a mastectomy, surgeons were more likely than non-surgeons to offer reconstruction (40% vs 16%). In a multiple logistic model controlling for all independent variables, this difference persisted (OR = 3.8, 95% CI = 1.4 - 10.4).

Length of time in practice influenced evaluation of a potential breast cancer and treatment of a known breast cancer. Physicians in practice a shorter time were more likely to obtain a tissue diagnosis for a potential breast cancer than physicians who had been in practice a longer time (91% vs 69%). In a multiple logistic model controlling for the estimated probability of breast cancer, physicians who had been in practice a shorter time remained more likely than those who had been in practice a longer time to obtain tissue for diagnostic purposes (OR = 6.1, 95% CI = 1.9 - 19.2). Physicians who were in practice a shorter time were more likely to perform full primary therapy for a women with a known breast cancer than physicians who had been in practice a shorter time (84% vs 67%). This difference persisted in a multiple logistic model controlling for all independent variables (OR = 2.8, 95% CI = 1.2 - 6.9).

The fear of malpractice did not influence the evaluation of a potential breast cancer or the treatment of a known breast cancer. It did, however, influence the evaluation of a known breast cancer. Physicians who performed an extensive metastatic evaluation had a greater concern over malpractice than those who did not (5.2 vs 3.9). This difference persisted in a multiple logistic model containing all study design variables (OR = 2.1, 95% CI 1.3 - 3.4). The odds ratio is calculated for a 3 point increase along the 10 point Likert scale rating fear of malpractice. Physicians who performed an axillary node dissection had greater concern over malpractice than those who did not (5.01 vs 4.17). This difference persisted in a multiple logistic model containing all study design variables (OR = 1.8, 95% CI = 1.1 - 3.0).

In summary, the previous completed studied concluded that poor, older and frail women received less aggressive management, while black women receive a more extensive metastatic evaluation and therapy to prevent metastases. Patient assertiveness had no direct bearing on physician decision making. Surgeons and older physicians were less aggressive in their care. The limitations of the previously completed study was the use of white male physicians in one geographic location. The specific aims of the current study are to address

the important factors of physician gender, race and geographic location in the decision making process.

5.5 Specific Aims

Recent data have shown that physician sex is a strong predictor of health services that women receive as patients. This study will build on our previous work on patient characteristics that are factors to appropriate diagnosis and treatment of breast cancer in women aged 65 and older. The primary question of focus for this study is:

1. How does physician gender influence the diagnosis and treatment of breast cancer in women?

Secondary questions to be explored in the analysis are:

2. What are the independent and joint influences of physicians' race, geographic location, practice specialty and age on (a) diagnosis, (b) treatment recommendations, and (c) referral patterns?

3. What are the independent and joint influences of patient age, race, socioeconomic status, comorbidity, and assertiveness on (a) diagnosis, (b) treatment recommendations, and (c) referral patterns for suspected and diagnosed breast cancer?

4. Can any variations in diagnosis and treatment patterns be explained by the interaction of patient and physician characteristics?

6.0 BODY

The methodology of the study will be outlined below, explaining 6.1) the unique fractional factorial experiment to control for patient characteristics, 6.2) the combined factorial and matching methodology for physicians selection as subjects and 6.3) the previous videotape development. The work performed to date will discuss 6.4) instrument development, 6.5) piloting, 6.6) development of sampling strategy for subjects in each of the three geographic areas, 6.7) consultants, and 6.8) preparatory activities. Planned activities for year 02 6.9) include development of training protocol for interviewers, and revisions to the previous timeline.

6.1 Fractional Factorial Experiment

In order to assess the independent effect of provider characteristics on patient management, we require a method to hold constant the clinical characteristics of the patient and vary only those aspects of the patient that we wish to assess. We have developed a unique experimental design, where clinical "patients" are developed for videotape and enacted

by actors to simulate patient-physician encounter. Versions of each videotape are produced that maintain the same clinical information while varying long those patient features as part of the experimental design.

In each of two medical scenarios, we shall investigate five patient factors: age, race, socioeconomic status, comorbidity and mobility. For simplicity of analysis, each factor is dichotomized. The patients enacted on videotape are either 65 or 80 years of age, and either black or white. Socioeconomic status is either upper-level or lower-level, as expressed by a complex of characteristics, including dress, idioms of speech, and coverage by Medex versus Medicaid health insurance. Comorbidity is dichotomized as a patient free of chronic illness, or one with stable hypertension and diabetes on oral medication.

The fifth patient factor has changed from the original grant proposal. Originally patient assertiveness was planned as one of the five patient factors for review. However, in the previously completed investigation (see 5.4), assertiveness was not found to have any direct effects with physician decision making. The additional characteristic varied in the completed study was mobility, which showed significant effects on physician decision making, and was therefore chosen to be studied in the current project. Mobility is defined as either no disabling condition, or frailty as a woman with osteoarthritis of the knees requiring the use of a walker.

The five patient characteristics are capable of 2x2x2x2x2=32 combinations, which would constitute a full factorial design. Using the principle of fractional factorial design (Cochran and Cox, 1957; Kirk, 1982) we have selected half that many combinations, balanced so that each factor or combination of two factors occurs half the time with each of the other factors. Thus the design required 8 actors to create 16 different "characters." Only five patient characteristics were chosen for the current research, as opposed to six in the previously completed investigation (see 5.3) in order to have sufficient power to investigate the role of physician gender, race and geographic location in the current research.

Each of the 16 "characters" enacts two scenarios. In the first scenario, the patient presents with a question of a new breast mass, seeking diagnostic evaluation. In the second scenario, the patient presents with a confirmed .8 cm carcinoma by excisional biopsy and seeks recommendations for completion of diagnostic evaluation, primary and adjuvant therapies. The total experimental set comprises 32 videotapes: 16 paired versions of Scenario 1 and Scenario 2. Each of the 16 pairs will include one of each scenario. The respective patients within each pair will differ with respect to all five patient characteristics: age, race, socioeconomic status, comorbidity and mobility. Each taped pair will remain together throughout the experiment.

6.2 Physician Characteristics and Study Population Selection

The character of the physician on videotape is invariant across all patients and scenarios. What we plan to vary by stratification and pairing are the characteristics of the

physicians to whom the tapes are shown. Ideally we would have chosen a factorial design to investigate physician factors. However, it is unlikely that we will be able to fill all cells, especially with black physicians. Therefore, we chose to use matched pairs of male and female physicians to study our primary variable of interest, matching to control for other variables.

The highest stratum of the sample is geographic location. Three sites have been selected, each centered in a metropolitan area with a substantial population of female and minority physicians. Within each site, 32 female physicians will be recruited. Black physicians will be over-sampled, in order to provide enough statistical power to make inferences about those factors.

For each female physician agreeing to the experiment, a matching male physician will be recruited. The matching man will view the same videotape scenarios as his female counterpart, in an independent session. The matching criteria will be race, age, locale and specialty. Within each site, the 32 matched pairs of physicians will be assigned at random to view one of 16 pairs of videotapes, in such a way that each videotape pair is used exactly twice per site. Thus we shall combine a half-factorial on 5 patient characteristics with equal numbers of matched female and male physicians in each of the 3 locales, and stratification on the physician's secondary characteristics.

The population from which the sample will be selected has been deliberately chosen to maximize the generalizability of inferences while retaining a feasible research design. It consists of medical oncologists, general surgeons and surgical oncologists, specialists who provide diagnostic and therapeutic services for women with breast cancer. In the previous study gynecologists and radiation oncologists were also included in the sampling frame. They are now excluded for two reasons. Gynecologists in major metropolitan areas rarely perform breast biopsies and no longer perform mastectomies. Experience from our previous investigation (see 5.3) revealed that only six gynecologists were eligible out of 223 (< 3%) who were screened for eligibility. Radiation oncologists were excluded at this point, as they reported in the previous study that the first case was atypical of the patients they see in clinical practice. Removing these groups will maintain our generalizability while improving the ability to find eligible physicians to enroll as subjects.

The 3 statistical metropolitan areas, Detroit, Atlanta, and San Francisco/Oakland, were chosen to increase the power of the study and based on the following considerations:

1) Women physicians are more likely to practice in large metropolitan areas.

2) The three areas have relatively high numbers and proportions of black physicians (3.6 - 8.1% male physicians, and 8.4 - 18.2% women physicians) based on 1990 Population Census Employment (EEO) file on the civilian labor force.

3) The three areas represent geographic areas with high (San Francisco/Oakland), moderate (Detroit), and low (Atlanta) utilization of breast conserving surgeries (Nattinger 1992, Farrow 1992).

4) Focusing on large metropolitan areas will decrease the cost and difficulty of reaching physicians in their offices for the study. It will however limit our ability to generalize our findings to rural physicians.

Estimates of number of eligible physicians are based on AMA master files of all licensed physicians and 1990 EEO employment files for estimates of minority physicians. Based on previous studies where 75% of physicians listed meet eligibility criteria, and estimating a 60% response rate (a conservative estimate, given the previous study's 88% response rate) we anticipate sufficient subjects for a balanced number of physicians in most cells and reduced numbers in cells of older female physicians in Atlanta, and female medical specialists and black physicians in all locales, with at least 25% of the total sample as black physicians.

6.3 Videotape Development

Funding from the National Institute of Aging (AG11352) enabled us to professionally produce two sets of videotapes for use in this project. One scenario involves a woman presenting with a possible breast mass, the second scenario involves a women with Stage IIA breast cancer. Strict quality control insured that the dialogue, non-verbal expressions and clinical information in each version of the videotapes remain constant, varying only those patient characteristics of interest for the study. (see 5.3)

6.4 Instrument Development

An extensive interviewer-administered and self-administered interview instrument was developed for the previous study (see 5.3). The structured interviewer-administered instrument asked about physicians' differential diagnoses, and evaluation strategy in the scenario of the patient presenting with a possible breast mass. For the second scenario of a biopsy-proven breast cancer, the instrument reviewed physicians' evaluation and treatment strategies. The self-administered questionnaire included scales on attitudes towards race, age, and gender, concern over malpractice, and comfort with levels of uncertainty and chance.

Revisions were completed on both the interviewer administered and the self administered instruments. The revisions to the interviewer administered and self-administered instruments dealt with the following issues raised by both the unique study objectives of the current study, as well as building upon the findings of the previous study.

1) Use of new guidelines in evaluation of a breast mass. The first case dealing with the patient with a possible breast mass required inclusion of concepts developed in the past two years on the appropriate management of breast masses. Fine needle aspiration biopsy and stereotactic core biopsy were not universally available at the time of the

completed investigation, however, these have now become standard of care (CDC, 1995). We have retained our original questions about whether core biopsy or fine needle aspiration biopsy are used, but have also included questions to probe the reasoning behind the use of these various tests.

2) The use of adjuvant therapies. Since our previously completed investigation, the use of tamoxifen has come under intense scrutiny, in terms of its efficacy as corrections to the original clinical trials became public, and the incidence of endometrial cancer and deep vein thrombosis with its use (Angell, 1994; Crewdson, 1994; Fisher, 1994; NCI, 1994; Poisson, 1993). The findings of our completed investigation indicated that black women received more tamoxifen and chemotherapy, that poorer and older women received less chemotherapy. We have added questions in the interviewer administered questions to explore the reasoning behind the use of various forms of adjuvant therapy, in order to more clearer interpret our findings.

3) The role of clinical trials. The completed study asked one question about enrollment in trials, with little response. Since it is a current high priority area of the National Action Plan on Breast Cancer to better understand reasoning around trial enrollment, we have added an additional section of questions to explore the barriers to clinical trials and to determine to how the patient characteristics explored in this experimental study design influence physician decision making around clinical trial enrollment.

4) Assessment of racial attitudes. In the self-administered questionnaire of the previous study of white, male physicians, we included a scale on attitudes towards blacks in our society. Although the scale showed wide variability among physicians, we did not find that variability along this dimension explained differences in care provided, particularly the differences seen in the recommendation to black patients.
In the current study where we are studying both black and white physicians, the previous questions geared towards racial feeling of whites towards blacks were not appropriate. Review of the literature of racial attitude scales revealed no appropriate measures for this diverse population (Felder, 1990; Gaertner, 1983; Kessler, 1986; Pico, 1992; Rooda, 1992; Swim, 1995). Consultation with an outside sociologist with expertise in questionnaire design along racial attitudes was obtained. Rosalyn Barrow, PhD, a Radcliffe Bunting Fellow, has extensive expertise in questionnaire development on minority issues. She corroborated our finding that a validated scale on racial attitudes useful more minority and majority groups does not exist. Given the strength of experimental design to investigate differences in management of patient among racially congruent and racially divergent patient-physician diads, we chose to ask no further racial attitude questions.

5) Because of the important findings on practice patterns and concern with malpractice, we added to the self-administered interview several validated scales, most not available at the time of the previous investigation. We have included scales of a) cost -consciousness, b)fear of malpractice, c) discomfort with uncertainty, developed using

factor analysis and validated on a broad sample of primary care providers and subspecialists (Goold et al 1994). An additional scale d) reluctance to disclose uncertainty was also added (Gerrity et al 1990).

6.5 Piloting

The questionnaire was piloted in its complete form with 12 physicians of diverse backgrounds to assess for the comprehensibility and acceptability of the new questions and the questionnaires in their entirety. All pilot administration were performed with at least two observers present, including the principal investigator. Subject difficulties in comprehension of the intent of questions was in particular examined. Revisions were made based on the comments of the pilot subjects on an ongoing basis during the pilot phase, so that revisions of poorly worded questions could then be piloted. Appendices 1 and 2 contain the final instruments.

6.6 Sampling Strategy

Our previous investigation revealed that the AMA masterfile of physicians have significant updating difficulties, resulting in underrepresentation of newly licensed or relocated physicians, and resulted in significant inefficiencies in locating potentially eligible physicians. We have purchased tapes from each of the state licensing boards of currently licensed physicians. The tape includes the following information on each provider: office address, gender, primary and secondary specialties and subspecialties, year of graduation from medical school. This provides us with all but race information to initially select physicians for eligibility.

Information about physician race is not obtainable from this or any other commercially available listing of physicians. We have developed a strategy of obtaining a list of black physicians from our consultants in each geographic location (see 6.7). Given the interactions within the medical and surgical oncology communities, we anticipate that each consultant will be able to provide us with a complete list of practicing black physicians in the specialties listed above, and our randomization will occur from this list.

6.7 Consultants

Three consultants have been recruited from each of the three geographic areas of data collection to assist with the project. Criteria required of our consultants were a broad based knowledge of the medical practice community in their area, the academic stature to assist in recruitment efforts, and sufficient relationships within the oncology and surgical communities to identify a list of black physicians in practice in their are. All three consultants are all well qualified to assist in the tasks necessary for the project.

Laura Esserman MD is a general and breast surgeon at University of California at San Francisco and staff member of their Breast Cancer Center. Having completed all her

graduate and post-graduate medical training in the San Francisco Bay Area, and with her involvement with interinstitutional breast cancer conferences, she brings her knowledge of local practice patterns, and extended network of contacts in oncology.

Bruce McCarthy MC MPH is division head in internal medicine at Henry Ford Health System in Detroit. As an division head at the largest health maintenance organization in the Detroit area, he brings his contacts within the organization and beyond to assist in the research program.

Christopher Lockhart MD is an internist and faculty member at Emory University School of Medicine. In addition to his contacts through the Emory University system, his involvement with organizations of physicians of color will assist in our ability to identify and recruit black physicians to the study.

All consultants have agreed to take on the following functions:

1) Finding minority physicians -- we have been able to obtain a list of licensed physicians by specialty and gender from the each of the boards of registration for Georgia, California and Michigan, but are not allowed access to lists of minority physicians through the National Medical Society or other groups. Each consultant has agreed to assist through their contacts for names of black women and men in the required specialties, and their contacts of minority physician organizations to obtain such names. Such assistance in recruitment will be of great assistance in the screening process of potentially eligible providers.

2) Piloting the instrument-- Each consultant will pilot the entire instrument. They will provide feedback with regard to any local issues we should address. They will also serve as an additional training interview for each of the interviewers prior to data collection.

3) Information on local practice patterns -- These consultants have provided important information about practice patterns in their community, such as the issue of one-step biopsy- mastectomy procedures, whether gynecologists in their area perform breast surgery and should by included in the sampling frame. They have also assisted in logistic help, such as how to secure parking for interviewers when they present with their equipment to conduct the interviews.

4) Editing and co-signing introductory letter -- Consultants will develop the introductory letter to physicians asking their participation on their own stationary with their signature in addition to that of the principal and co-principal investigators. We have found that having a local physician involved improves the response rate by physicians asked to participate.

5) Contact person for physicians with questions -- The consultants will serve as the contact person for potential subjects who have additional questions about the study before agreeing to participate. This will also serve to increase the response rate.

6) Contact non-responders -- When study staff are unsuccessful in reaching a physician randomly chosen to participate, the consultant will place at least 3 calls to that physician's office to participate

6.8 Other Preparatory Activities

Institutional Review Board -- Approval has been applied from and granted from the Boston University Medical Center Hospital IRB (Appendix 4).

6.9 Planned Activities for Project Year 02

6.9.1 *Training of the Interviewers*

Three interviewers from the three locations of the study have been recruited to perform the in person interviews; Rebecca Vaughn, B.A. in Atlanta, Susan Scheffield M.A. in San Francisco, and Kenneth Schreiner, M.A. in Detroit. All have extensive interviewing experience. Appendix 3 gives the schedule of the planned 3 day training seminar. The seminar will cover general interviewing techniques and standardized probes. Background on breast cancer treatment and specifics about treatment as they relate to the questionnaire, including a glossary of terms will be reviewed. The questionnaire will be reviewed and discussed in detail. Each interviewer will observe one interview. Each interviewer will then administer 2 mock interviews with standardized 'subjects', two of the investigators who will answer in a standard method so as to address the most common problems encountered. Each interviewer will complete one further mock interview with the consultant in their area before beginning data collection.

6.9.2 *Revisions to Previous Timeline*

Our original proposal scheduled a timeline that staggered enrollment at the three geographic sties. However, the experience of the media and scientific discussion around the use of tamoxifen (Angell, 1994; Crewdson, 1994; Fisher, 1994; NCI, 1994; Poisson, 1993) alerted us to the possibility of secular trends that could differentially affect geographic sites with even a small amount of staggering of the enrollment schedule. Our revised timeline for 1995 is as follows:

Activity	Months
Training of Field Staff	12 - 14
In-person Interviews site 1	

a) 24 interviews completed 14 - 20

b) 40 interviews completed 20 - 24

In-person interviews site 2

a) 24 interviews completed 14 - 20

b) 40 interviews completed 20 - 24

In-person interviews site 3

a) 24 interviews completed 14 - 20

b) 40 interviews completed 20 - 24

This revision in the timeline delays beginning of data collection at site 1 and accelerates the beginning at site 3. The overall rate of recruitment remains the same, and will not delay completion of data collection.

7.0 CONCLUSIONS

Because the current project is as yet not complete, there are currently no conclusions to be drawn about the study. The study is currently on time and in the data collection phase.

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9.0 APPENDICES

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2) Self-Administered Questionnaire

3) Schedule for Training of Interviewers

4) Institutional Review Board Approval and Consent Form

APPENDIX 1

INTERVIEWER-ADMINISTERED QUESTIONNAIRE

rev 9/28/95

BREAST DISEASE AND DECISION MAKING:

Interviewer-Administered Questionnaire

DATE: _____
TIME BEGAN: _____

A. INTRODUCTION

First of all, thank you very much for taking time out to speak with us. We really appreciate your help.

As you know, this study is supported by the Department of Defense and is being conducted by New England Research Institute for which I work, and in collaboration with Boston University Medical Center. During this hour I will be showing you two videotaped doctor-patient interviews. After each one, I will ask you what you would typically do if this patient came to see you. I'll ask about your working diagnoses (if any), treatment plans and what types of issues you normally consider for each of these cases. At the end, I'll ask you some more general questions about your background, your practice, and the types of patients you typically see.

Before we get started, I need you to sign this form. As you can see confidentiality is guaranteed and you will never be identified in a report. **[HAND FORM]** If you have any questions about it, please ask.

Do you have any questions before we begin?

There are no right or wrong answers. We're interested in what you would typically do in your practice.

B. PRE-WORKUP

You may take notes if you wish. I will show you each tape one time. **[SHOW TAPE]**

PT # _____

I. WORK-UP SHEET

These are the results from the mammogram.

[SHOW R WORK-UP SHEET]

We have the mammogram films available for you to review as well. **[HAND MAMMOGRAMS ONLY IF REQUESTED.]** Please look the report over and we'll continue when you're ready.

[PAUSE] **REVIEWS MAMMOGRAMS 1N 2Y**

II. SYNOPSIS

Before I begin asking you questions, I'd like you to dictate a brief synopsis of this patient's case. You should assume that you agree with the findings presented by the physician on the videotape, and that your complete physical exam would not reveal any new findings. Please leave out your assessment and recommendations - we'll get to that later. In other words, please summarize the information you have about the case to date.

NOTES: 1 NO 2 YES

III. EVALUATION

Now I will ask you further questions about your evaluation of this case based on the video and the information provided. Remember that there are no right or wrong answers; we're interested in what you would typically do for this patient and why.

1. Would you please state your major working diagnoses - listing up to 3 - telling me the most likely diagnosis first and the least likely last.

1_____
2_____
3_____

1= fibrocystic breast disease (FCD)
2= physiologic nodularity
3= breast cyst
4= fibroadenoma
5= breast cancer/carcinoma
6= normal breast examination, within normal limits
7= other, list....

A

If 0 is completely unlikely and 100 is completely likely, what are the chances that the patient has **[DIAGNOSIS]**? *[Note to interviewer: Chances do not have to equal 100%, but must not exceed 100%]*

B

What is the primary information about this case that led you to consider **[DIAGNOSIS]?[PROBE ONCE: Anything else?]**

2. Diagnosis 1

_____

_____

_____

_____

_____

_____

3. Diagnosis 2

_____

_____

_____

_____

_____

_____

4. Diagnosis 3

_____

_____

_____

_____

_____

_____

5. If you saw this patient in your everyday practice, following the mammogram, would you order diagnostic tests or x-rays?

1. No, would not order **(GO TO PAGE 9, "PATIENT MANAGEMENT")**
2. Yes, would order (If yes, go to 5b and c)
9. DK

5b. What would you order at the first visit, understanding you could order more tests after the results are known?

Test A:_____

Test B:_____

Test C:_____

Test D:_____

Test E:_____

Test F:_____

Test G:_____

Test H:_____

Test I:_____

Test J:_____

Test K:_____

Test L:_____

5c.(IF MORE THAN ONE TEST ORDERED, ASK)
Is one test most important? 1. YES 2. NO
Which one is it? _____

1= breast ulltrasound
2= mammography with special views
3= needle aspiration
4= fine needle aspiration biopsy(FNA)
5= chest x-ray (CXR)
6= bone scan
7= Liver Function Test (LFT)
8= head CT
9= calcium
10= alkaline phosphate
11= SGOT (ALT)
12= SGPT (AST)
13= Bilirubin
14= GGT
15= albumen
16= SMA6
17= SMA20
18= other, list

6. There are many reasons for ordering tests or x-rays. What would be your single most important reason for ordering **[TEST]** for this patient?

[BE SPECIFIC: "WHAT DO YOU MEAN", ETC.]

Test A:_____

Test B:_____

Test C:_____

Test D:_____

Test E:_____

Test F:_____

Test G:_____

Test H:_____

Test I:_____

Test J:_____

Test K:_____

Test L:_____

1= overall health
2= R/O mets
3= to differentiate cyst from solid mass
4= to determine extent of disease
5= better define characteristics of breast abnormality
6= to diagnose breast cyst
7= to diagnose breast cancer
8= to prepare for surgery
9= other, specify

These are the results from the diagnostic tests or x-rays which you would have ordered for this patient.

[HAND R ALL THE RESULTS FROM THE TESTS LISTED ON PAGE 4]

7. Taking these test results into account, would you order additional diagnostic tests or x-rays?

1. No, would not order **(GO TO QUESTION 11)** 2. Yes, would order 9. DK

7b. What would you order?

Test A:_____

Test B:_____

Test C:_____

Test D:_____

Test E:_____

1= breast ulltrasound
2= mammography with special views
3= needle aspiration
4= fine needle aspiration biopsy(FNA)
5= chest x-ray (CXR)
6= bone scan
7= Liver Function Test (LFT)
8= head CT
9= calcium
10= alkaline phosphate
11= SGOT (ALT)
12= SGPT (AST)
13= Bilirubin
14= GGT
15= albumen
16= SMA6
17= SMA20
18= other, list

8. There are many reasons for ordering tests or x-rays. What would be your single most important reason for ordering **[TEST]** for this patient?

[BE SPECIFIC: "WHAT DO YOU MEAN", ETC.]

Test A:_____

Test B:_____

Test C:_____

Test D:_____

Test E:_____

1= overall health
2= R/O mets
3= to differentiate cyst from solid mass
4= to determine extent of disease
5= better define characteristics of breast abnormality
6= to diagnose breast cyst
7= to diagnose breast cancer
8= to prepare for surgery
9= other, specify

These are the results from the diagnostic tests or x-rays which you would have ordered for this patient.

[HAND R ALL THE RESULTS FROM THE TESTS LISTED ABOVE IN ITEM 7]

9. Taking these test results into account, would you order additional diagnostic tests or x-rays?

1. No, would not order **(GO TO QUESTION 11)** 2. Yes, would order 9. DK

9b. What would you order?

Test A:_____

Test B:_____

Test C:_____

Test D:_____

Test E:_____

1= breast ulltrasound
2= mammography with special views
3= needle aspiration
4= fine needle aspiration biopsy(FNA)
5= chest x-ray (CXR)
6= bone scan
7= Liver Function Test (LFT)
8= head CT
9= calcium
10= alkaline phosphate
11= SGOT (ALT)
12= SGPT (AST)
13= Bilirubin
14= GGT
15= albumen
16= SMA6
17= SMA20
18= other, list

10. There are many reasons for ordering tests or x-rays. What would be your single most important reason for ordering **[TEST]** for this patient?

[BE SPECIFIC: "WHAT DO YOU MEAN", ETC.]

Test A:_____

Test B:_____

Test C:_____

Test D:_____

Test E:_____

1= overall health
2= R/O mets
3= to differentiate cyst from solid mass
4= to determine extent of disease
5= better define characteristics of breast abnormality
6= to diagnose breast cyst
7= to diagnose breast cancer
8= to prepare for surgery
9= other, specify

These are the results from the diagnostic tests or x-rays which you would have ordered for this patient.

[HAND R ALL THE RESULTS FROM THE TESTS LISTED ABOVE IN ITEM 9]

11. Based on the results of all these tests, would you please state your major working diagnoses - listing up to 3 - telling me the most likely diagnosis first and the least likely last.

1_____

2_____

3_____

1= Fibrocystic breast disease (FCD)
2= physiologic nodularity
3= breast cyst
4= fibroadenoma
5= breast cancer
6= normal breast exam
7= other, list

12. If 0 is completely unlikely and 100 is completely likely, what are the chances that the patient has: *[Note to interviewer: Chances do not have to equal 100%, but must not exceed 100%]*

DIAGNOSIS 1	____%
DIAGNOSIS 2	____%
DIAGNOSIS 3	____%

IV. PATIENT MANAGEMENT

1. What recommendation for evaluation and follow-up, if any, would you typically recommend after seeing this patient.
[DO NOT READ CATEGORIES. CHECK ALL THAT APPLY. RESPONDENT CAN NAME MORE THAN ONE. FOR MEDICATIONS, PROBE, " What would you prescribe and how much per day?"] [PROBE ONCE: "Is there anything else?"]

2. Would you discuss with the patient any alternative recommendation for evaluation and follow-up? ___a. NO ___b. YES
[IF YES, "WHAT": and check below]

1	2				
___	___	Return to referring physician for follow-up			
___	___	Return to this MD	___	___	in 3 months
			___	___	in 6 months
			___	___	in 12 months
			___	___	in other time:_____
___	___	Refer to other specialist (specify:_____)			
___	___	Return for mammogram			
			___	___	in 3 months
			___	___	in 6 months
			___	___	in 12 months
			___	___	in other time:_____
___	___	Return for special view mammogram			
			___	___	in 3 months
			___	___	in 6 months
			___	___	in 12 months
			___	___	in other time:_____
___	___	Return for ultrasound			
			___	___	in 3 months
			___	___	in 6 months
			___	___	in 12 months
			___	___	in other time:_____

A.	___	___	needle aspiration
B.	___	___	fine needle aspiration biopsy (FNA)
C.	___	___	core biopsy
D.	___	___	incisional biopsy
E.	___	___	excisional biopsy
F.	___	___	lumpectomy
G.	___	___	biopsy with mastectomy if frozen section positive
H.	___	___	mastectomy
	___	___	tamoxifen (dose_____)
	___	___	instruct in Breast Self-Exam (BSE)
	___	___	other, specify:_____
	___	___	no treatment necessary
	___	___	no follow-up necessary

3. (If A-H are NO). Would you consider obtaining any type of tissue evaluation at this initial evaluation?____NO____YES

3a. (If NO), what is the single most important reason you would not obtain a tissue evaluation at this point?(DO NOT READ OPTIONS)

1. ____low probability of cancer
2. ____elderly patient
3. ____negative mammogram
4. ____cost
5. ____other _____

3b. (If YES), what type?_____

4. (If A-H or 3b. chosen). There are currently many options for type of tissue evaluation. What is the single most important reason you would choose_____?(read physician's choice A-H or 3b. here)
(DO NOT READ OPTIONS)

a. ____outpatient
b. ____inexpensive
c. ____no general anesthesia
d. ____to make sure no cancer
e. ____sensitivity/specificity good
f. ____will give final answer
g. ____other _____

5. (If A-C or 3b. used): A. needle aspiration; B. fine needle aspiration biopsy (FNA); C. core biopsy
If the biopsy was negative, would you perform an open surgical biopsy?
(If YES), which type_____?
(If NO), what is your single most important reason for not performing the open surgical biopsy?(DO NOT READ OPTIONS)

a. ____cancer nearly ruled out
b. ____cancer ruled out
c. ____expensive
d. ____patient's age
e. ____risk of surgery/anesthesia not worth benefit
f. ____other _____

6. How would you describe the availability of each of the following tests?(READ ALL OPTIONS)

A. ____ needle aspiration
B. ____ fine needle aspiration biopsy (FNA)
C. ____ stereotactic core biopsy

1 = I do it myself in this office
2 = I do it myself but elsewhere
3 = It is done by a colleague in my institution
4 = I would refer the patient outside my institution
5 = I would not know where to have this procedure done

7. How would you describe your style of presenting treatment or management options?

(READ ALL OPTIONS)

A. _____ I offer options to all patients
B. _____ I offer options to some patients
C. _____ I do not offer options

8. How would you describe your style of presenting treatment or management recommendations? (HAND PHYSICIAN NOTECARD 1)

1. _____ I would only offer the treatment I would perform myself
2. _____ I would strongly recommend the treatment I would perform myself
3. _____ I would strongly recommend my treatment choice
4. _____ I would recommend my treatment choice, but encourage patient to consider options
5. _____ I would allow patient to choose without a recommendation

9. *(Note to interviewer: read option A if physician viewed 65 year old patient or option B if saw 80 year old patient)*

Considering her overall health, and given that the average woman age **A** [65 will live 16.5 additional years] ***B*** [80 will live 8 additional years], how many additional years of life do you think this patient has? _____

10. On a scale of 1 to 5, with 1 being low quality and 5 being high quality, given the patient's present condition how would you describe the patient's current quality of life?

low quality.....high quality
1 2 3 4 5

11. How typical is this patient of patients you normally see in your practice? Would you say she is:

1 very typical
2 somewhat typical
3 somewhat atypical
4 very atypical

11b. How is this patient atypical?

_____
_____

12. If you were seeing this patient in your office, would your initial approach be any different than that of the doctor in the videotape or would it be the same?

1. Same 2. Different

12b. How would it be different? **[DO NOT READ CATEGORIES. CHECK ALL THAT APPLY. PROBE ONCE: Any other ways?]**

___ ASK MORE HISTORICAL QUESTIONS
___ ASK MORE SOCIAL HISTORY QUESTIONS
___ PERFORM MORE COMPLETE PHYSICAL EXAM
___ ESTABLISH MORE OF A RELATIONSHIP
___ REASSURE THE PATIENT
___ GIVE THE PATIENT IMMEDIATE FEEDBACK/INFO ON CONDITION
___ OTHER, RECORD BELOW:

_____
_____
_____

C. POST- WORKUP

PT #_____ **[SHOW TAPE]**

I. WORK-UP SHEET

Now that you have seen the doctor-patient interview, please examine the results from the pathology report and the physical examination.

[SHOW R 1) Path report--left breast mass 2) hormone receptors 3) physical exam]

Please look these over and we'll continue when you're ready.

[PAUSE]

II. SYNOPSIS

Before I begin asking you questions, I'd like you to dictate a brief synopsis of this patient's case. I'd like you to include all the information you normally would provide in the patient's file if you were sending a letter to the referring physician. In other words, please summarize the case to date and leave out your treatment plans for now. We'll get to that in a mome

NOTES: 1N 2Y

III. EVALUATION

Now I will ask you further questions about your evaluation of this case based on the video and the information from the work-up. Assume that you will want to obtain any further evaluation necessary to plan both the primary therapy and any adjuvant therapy for this patient. Remember that there are no right or wrong answers; we're interested in what you would typically do for this patient and why.

1. If you saw this patient in your everyday practice, which diagnostic tests, x-rays, or operative procedures would you initially perform understanding that you could perform other procedures later?

1. No, would not perform **(GO TO PAGE 16 - "PATIENT MANAGEMENT")** 2. Yes would perform 9. DK

1b. What would you initially perform?

Test A:_____

Test B:_____

Test C:_____

Test D:_____

Test E:_____

Test F:_____

Test G:_____

Test H:_____

Test I:_____

Test J:_____

Test K:_____

Test L:_____

1c.(IF MORE THAN ONE TEST ORDERED, ASK)
Is one test most important? 1 YES 2 NO Which is it? _____

1= axillary node dissection
2= bone scan
3= cardiac echo/ultrasound
4= CBC
5= chest X-ray knees, spine
6= CT Scan - body/abdomen
7= CT Scan - head
8= EKG/ECG (electrocardiogram)
9= LFT (liver function tests)
10= right upper quadrant/abdominal ultrasound
11= Mammogram
12= MRI- head/brain
13= pulmonary function tests
14= SMA6 (electrolytes)
15= SMA20
16= Calcium
17= Phosphate
18= SGOT (ALT)
19=SGPT (AST)
20=GGT
21=Alkaline phosphatase
22=Albumen
23=CA125
24=plain films (xrays) of
25=glycosylated hemoglobin
26=DNA analysis
27=other, specify
28=p53
29=CEA

(IF TEST NOT LISTED, PROMPT "IS THIS TEST CALLED BY ANOTHER

NAME?)

2. There are many reasons for performing tests, x-rays or operative procedures. What would be your single most important reason for performing **[TEST]** for this patient?

[BE SPECIFIC: "WHAT DO YOU MEAN", ETC.]

Test A:_____

Test B:_____

Test C:_____

Test D:_____

Test E:_____

Test F:_____

Test G:_____

Test H:_____

Test I:_____

Test J:_____

Test K:_____

Test L:_____

1= establish **baseline** prior to chemotherapy
2= assess overall **health** status
3= Rule out **mets**
4= assess **prognostic** indicators
5= establish **baseline** for future
6= **pre-operative** evaluation
7= **staging** of tumor
8= R/O **second primary breast CA**
9= planning future **treatment**
10=other, specify

These are the results from the diagnostic tests, x-rays or procedures, which you would have performed for this patient.

[HAND R ALL THE RESULTS FROM THE TESTS LISTED ON PAGE 12]

3. Taking these test results into account, would you perform additional diagnostic tests, x-rays or operative procedures at this point to determine your definitive management plan? **[NOTE: IF R OFFERS A TREATMENT, PROBE FOR DIAGNOSTIC TESTS, X-RAYS OR OPERATIVE PROCEDURES.]**

1. No, would not perform **(GO TO PAGE 17 - "PATIENT MANAGEMENT")**
2. Yes, would perform
9. DK

3b. What would you perform?

Test A:_____

Test B:_____

Test C:_____

Test D:_____

Test E:_____

1= axillary node dissection
2= bone scan
3= cardiac echo
4= CBC
5= chest X-ray
6= CT Scan - body
7= CT Scan - head
8= EKG
9= LFT
10= right upper quadrant ultrasound
11= Mammogram
12= MRI- head
13= pulmonary function tests
14= SMA6
15= SMA20
16= Calcium
17= Phosphate
18= SGOT (ALT)
19=SGPT (AST)
20=GGT
21=Alkaline phosphate
22=Albumen
23=CA125
24=plain films of knees,spine
25=glycosylated hemoglobin
26=DNA analysis
27=other, specify

4. What would be your single most important reason for performing **[TEST]** for this patient? **[BE SPECIFIC: "WHAT DO YOU MEAN", ETC.]**

Test A:_____

Test B:_____

Test C:_____

Test D:_____

Test E:_____

1= establish **baseline** prior to chemotherapy
2= assess overall **health** status
3= Rule out **mets**
4= assess **prognostic** indicators
5= establish **baseline** for future
6= **pre-operative** evaluation
7= **staging** of tumor
8= R/O **second primary breast CA**
9= planning future **treatment**
10=other, specify

These are the results from the diagnostic tests, x-rays or operative procedures, which you would have performed for this patient. **[HAND R ALL THE RESULTS FROM THE TESTS LISTED ABOVE IN ITEM 3]**

5. Taking these test results into account, would you perform additional diagnostic tests, x-rays or operative procedures at this point?

1. No, would not perform 2. Yes, would perform 9. DK

(GO TO PAGE 17 - "PATIENT MANAGEMENT")

5b. What would you perform?

Test A:_____

Test B:_____

Test C:_____

Test D:_____

Test E:_____

1= axillary node dissection	10= right upper quadrant ultrasound	19=SGPT (AST)
2= bone scan	11= Mammogram	20=GGT
3= cardiac echo	12= MRI- head	21=Alkaline phosphatase
4= CBC	13= pulmonary function tests	22=Albumen
5= chest X-ray	14= SMA6	23=CA125
6= CT Scan - body	15= SMA20	24=plain films of knees,spine
7= CT Scan - head	16= Calcium	25=glycosylated hemoglobin
8= EKG	17= Phosphate	26=DNA analysis
9= LFT	18= SGOT (ALT)	27=other, specify

6. What would be your single most important reason for performing **[TEST]** for this patient? **[BE SPECIFIC: "WHAT DO YOU MEAN", ETC.]**

Test A:_____

Test B:_____

Test C:_____

Test D:_____

Test E:_____

1= establish **baseline** prior to chemotherapy	7= R/0 **second primary breast CA**
2= assess overall **health** status	8= **staging** of tumor
3= Rule out **mets**	9= planning **future treatment**
4= assess **prognostic** indicators	10=other, specify
5= establish **baseline** for future	
6= **pre-operative** evaluation	

These are the results from the diagnostic tests, x-rays or operative procedures, which you would have performed for this patient.

[HAND R ALL THE RESULTS FROM THE TESTS LISTED ABOVE IN ITEM 5]

IV. PATIENT MANAGEMENT

1. What treatment or management plan would you typically recommend after seeing this patient? Please tell me both what primary therapy as well as any adjuvant therapy you would recommend to treat this patient.

2. Would you discuss with the patient any alternative management plan? Please tell me both what primary therapy as well as any adjuvant therapy you would offer as alternative therapy to your first recommendation.

3. Would you discuss with the patient any other alternative management plan? Please tell me both what primary therapy as well as any adjuvant therapy you would offer as alternative therapy to your previous recommendations.

4. And would you discuss with the patient any other alternative management plan? Please tell me both what primary therapy as well as any adjuvant therapy you would offer as alternative therapy to your previous recommendations.

[DO NOT READ CATEGORIES. NUMBER ALL THAT APPLY. (1= FIRST RECOMMENDATION, 2= SECOND, 3= THIRD, 4= FOURTH)]
[IF 1ST CHOICE = NODE DISSECTION, GO BACK TO BEGINNING; Q5 PAGE 16]

1	2	3	4	Axillary node dissection
1	2	3	4	Simple mastectomy
1	2	3	4	Modified radical mastectomy
1	2	3	4	Radical mastectomy
1	2	3	4	Wedge resection
1	2	3	4	Lumpectomy
1	2	3	4	Reconstructive surgery
1	2	3	4	Chemo Rx (type,length_____)
				(type, length_____)
1	2	3	4	Tamoxifen (dose:_____)
1	2	3	4	Radiation therapy (type & dose_____)
				(type & dose_____)
1	2	3	4	Randomized clinical trial, specify:_____
				specify:_____
1	2	3	4	other,specify:_____
1	2	3	4	other, specify:_____
1	2	3	4	other, specify:_____

5. (IF 1st COICE IS MASTECTOMY) Do you consider this patient to be a candidate for breast conserving surgery?
   1 NO 2 YES
   Why not?(DON'T READ OPTIONS)

   a. _____ patient too old
   b. _____ tumor too large
   c. _____ high risk of recurrance
   d. _____ other

6. If you were to perform a mastectomy on this patient, would you offer reconstruction?
   1 NO 2 Only if patient asks for it 3 YES

   Please tell us the most important reason for you. _____
   (DON'T READ OPTIONS)

   a. _____ patient too old
   b. _____ chance of recurrence high
   c. _____ risk too great for additional surgery
   d. _____ poor cosmetic outcome
   e. _____ other _____

7. There has been a lot of debate around when to perform a lymph node dissection. Your choice _____ was _____ was not to perform the dissection. What was your most important consideration?

Why not?	Why?
a. _____patient too old	aa. _____ patient age appropriate
b. _____risk outweighs benefit	bb. _____ risk doesn't out-weigh benefit
c. _____would not change management	cc. _____ would change management
d. _____difficult recovery for patient	dd. _____ recovery not difficult
e. _____other _____	

8. On the following scale, how would you describe your style of presenting treatment or management recommendations?_____(HAND PHYSICIAN NOTECARD 2)

   1 = I would offer patient all options
   2 = I would offer options only if the patient requests them
   3 = I would offer options, but emphasize my choice
   4 = I would offer options, but would only perform my treatment choice
   5 = I would not offer options

9. In your everyday practice, would you consult any other specialist about this patient at this point, or would you treat her yourself?

1. Treat patient 2. Consult

9b. What type of specialist would you consult?

_____
_____
_____
_____

1= plastic surgeon
2= psychiatrist
3= radiation oncologist
4= surgical oncologist
5= medical oncologist
6= internist
7= cardiologist
8= pulmonologist
9= gynecologist
10=geriatrician
11=other specify

10. Doctors are divided on tamoxifen use. Why did you/didn't you offer this treatment?

Did	Did not
a. _____Cost low	aa.____ Cost High
b. _____Estrogen/Progestin receptors positive	bb._____Estrogen/Progestin receptors too low
c. _____Chance of recurrence low	cc. _____Not proven for this stage of cancer
d. _____Patient age appropriate	dd. _____Chance of recurrence high
e. _____Covered by insurance	ee. _____Patient too old
f. _____Other _____	ff. _____Not covered by insurance
	gg._____Other_____

11. Chemotherapy use is also controversial. Why did you/didn't you offer this treatment?

Did	Did not
a. _____Cost low	aa. _____Cost high
b. _____Estrogen/Progestin receptors negative	bb._____Estrogen/Progestin receptors positive
c. _____Risk does not outweigh benefits	cc. _____Risk outweighs benefit
d. _____Patient age appropriate	dd. _____Patient too old
e. _____Other _____	ee. _____Not covered by insurance
	ff. _____Not proven
	gg. _____Other _____

12. Radiation therapy is also a matter of choice. Why did you/didn't you offer this treatment?

Did	Did not
a. _____Patient not frail	aa. _____Patient too frail
b. _____Patient age appropriate	bb. _____Patient too old
c. _____Cost low	cc. _____Too expensive
d. _____Risk of recurrence high	dd. ____Risk of recurrence low
e. _____Other _____	

13. *[Note to interviewer: Read option A if physician viewed 65 year old patient or option B if saw 80 year old patient]*

Considering her overall health, and given that the average woman age **A** [65 will live 16.5 additional years]; **B** [80 will live 8 additional years], how many additional years of life do you think this patient has? _____

14. On a scale of 1 to 5, with 1 being low quality and 5 being high quality, how would you describe the patient's present quality of life?

low quality.....high quality
1 2 3 4 5

15. How typical is this patient of patients you normally see in your practice? Would you say she is:

1	very typical	3	somewhat atypical
2	somewhat typical	4	very atypical
		16b.	How is this patient atypical?

_____
_____

16. If you were seeing this patient in your office, would your initial approach be any different than that of the doctor in the videotape or would it be the same?

1. Same

2. Different

16b. How would it be different? **[DO NOT READ CATEGORIES. CHECK ALL THAT APPLY. PROBE ONCE: Any other ways?]**

___ ASK MORE HISTORICAL QUESTIONS
___ ASK MORE SOCIAL HISTORY QUESTIONS
___ PERFORM MORE COMPLETE PHYSICAL EXAM
___ ESTABLISH MORE OF A RELATIONSHIP
___ REASSURE THE PATIENT
___ GIVE THE PATIENT IMMEDIATE FEEDBACK/INFO ON CONDITION
___ OTHER, RECORD BELOW:

_____

_____

_____

Now I would like to ask you some specific questions regarding clinical trials.

1. Do you enroll patients in clinical trials?
   1 yes 2 no (IF NO, GO TO QUESTION 6)

   1b. (If YES) How many patients have you enrolled in the past year?_____

2. Do you belong to a clinical trials cooperative group?
   1 yes 2 no

   2b. (If YES) To which group(s) do you belong?_____

3. Do you have an Invesigational New Drug (IND) license?
   1 yes 2 no

4. Are you an independent trial investigator?
   1 yes 2 no

   4b. (If YES) Do you do surgical or drug investigations?_____

5. (If 1 is YES) Typically, when you offer a trial to a patient, who describes the trial in detail to the patient?

   ___ a. I do it myself
   ___ b. a research nurse
   ___ c. a fellow
   ___ d. other_____

   (*SKIP TO QUESTION 9*)

6. Does your institution currently offer any clinical trials?
   1 yes 2 no

7. Do you refer patients for clinical trials?
   1 yes 2 no

8. How many patients have you referred for trials in the past year?_____

9. Where do you receive information about current clinical trials?

   ___ a. Clinical Trials publications (NSABP, SWOG, etc)
   ___ b. Conferences/meetings
   ___ c. Colleagues who are conducting trials
   ___ d. Consultants in my institution
   ___ e. Journals
   ___ f. Other_____

10. Are you aware of any current clinical trials available in your area which may be appropriate for the patient in this second videotape?

a._____
b._____
c._____

11a. Would you offer _____ (read physician's answer to Q10a here) to this patient as a viable treatment option?

1. yes 2. no

(If NO) Why not? (DON'T READ CHOICES)

___ a. Patient too old
___ b. Chance of recurrence low
___ c. Risks too high
___ d. Patient too immoble
___ e. Outcome uncertain
___ f. Prefer not to refer case
___ g. Costs not covered by trial
___ h. Other_____

(If YES)Why? (DON'T READ CHOICES)

___ aa. Age is appropriate
___ bb. Chance of recurrence high
___ cc. Risk is low
___ dd. Patient has good mobility
___ ee. Outcome reasonably certain
___ ff. Prefer to refer case
___ gg. Costs covered by insurance
___ hh. Other_____

11b. Would you offer _____ (read physician's answer to Q10b here) to this patient as a viable treatment option?

1. yes 2. no

(If NO) Why not? (DON'T READ CHOICES)

___ a. Patient too old
___ b. Chances of recurrence low
___ c. Risks too high
___ d. Patient too immoble
___ e. Outcome uncertain
___ f. Prefer not to refer case
___ g. Trial not covered by insurance
___ h. Other_____

(If YES)Why? (DON'T READ CHOICES)

___ aa. Age is appropriate
___ bb. Chance of recurrence high
___ cc. Risk is low
___ dd. Patient has good mobility
___ ee. Outcome reasonably certain
___ ff. Prefer to refer case
___ gg. Costs covered by trial
___ hh. Other_____

11c. Would you offer _____ (read physician's answer to Q10c here) to this patient as a viable treatment option?

1. yes 2 no

(If NO) Why not? (DON'T READ CHOICES)

___ a. Patient too old
___ b. Chances of recurrence low
___ c. Risks too high
___ d. Patient too immoble
___ e. Outcome uncertain
___ f. Prefer not to refer case
___ g. Trial not covered by insurance
___ h. Other_____

(If YES) Why? (DON'T READ CHOICES)

___ aa. Age is appropriate
___ bb. Chance of recurrence high
___ cc. Risk is low
___ dd. Patient has good mobility
___ ee. Outcome reasonably certain
___ ff. Prefer to refer case
___ gg. Costs covered by trial
___ hh. Other_____

12. When seeing a patient like the one you saw in the video, how important are the following when considering her appropriateness for a clinical trial?(HAND PHYSICIAN NOTECARD 3)

1= very important
2= somewhat important
3= neither important nor unimportant
4= somewhat unimportant
5= unimportant

a. Patient age	1	2	3	4	5
b. Patient's physical mobility	1	2	3	4	5
c. Patient comorbidities	1	2	3	4	5
d. Patient's social supports	1	2	3	4	5
e. Patient's ability to pay for additional trial expenses	1	2	3	4	5
f. Patient's ability to understand implications of trial and give informed consent	1	2	3	4	5
g. Projected level of patient compliance	1	2	3	4	5

13. Based on your experience with your own patients, how likely do you think the patient in the videotape is to:(HAND PHYSCIAN NOTECARD 4)

1 = not likely
2 = somewhat unlikely
3 = neither unlikely nor likely
4 = somewhat likely
5 = very likely

a. Understand the implications of participation in a clinical trial?	1	2	3	4	5
b. Agree to participate in a trial?	1	2	3	4	5

14. Suppose that the patient in the second video had 3 of 29 positive lymph nodes. One clinical trial currently available in your area for post menopausal women with Stage II breast cancer investigates whether a dietary fat reduction in conjunction with cytoxan, shows an impact on recurrance. Would you encourage the patient in the video to enroll in this trial?

1. yes 2. no

14b. (If NO)Why not? (DON'T READ CHOICES)

___ a. Patient too old
___ b. Chance of recurrance low
___ c. Risks too high
___ d. Outcome uncertain
___ e. Cost
___ f. I don't refer to clinical trials
___ g. Other_____

(If YES)Why? (DON'T READ CHOICES)

___ aa. improved survival
___ bb. good of society
___ cc. easier to monitor patient
___ dd. costs covered by trial
___ ee. Other_____

15. Another trial available in your area for pre or post-menopausal women with 0-3 lymph nodes positive treats participants with 3 doses of adriamycin with cytoxan, with or without Taxol. Supposing she had 3 of 29 lymph nodes positive, would you encourage the patient in the second video to enroll in this trial?

1. yes 2. no

15b. (if NO) Why not?
(DON'T READ CHOICES)

___ a. Patient too old
___ b. Chance of recurrance low
___ c. Risks too high
___ d. Outcome uncertain
___ e. Cost
___ f. Other_____

(If YES)Why?
(DON'T READ CHOICES)

___ aa. improved survival
___ bb. good of society
___ cc. easier to monitor patient
___ dd. age is appropriate
___ ee. other_____

16. In your practice, how frequently do you encounter the following barriers when you consider recommending a clinical trial?(HAND PHYSICIAN NOTECARD 5)

1= all of the time
2= very often
3= half of the time
4= not very often
5= never

a. Patient's uninsured medical costs	1	2	3	4	5
b. Patient's uninsured trial-related costs (i.e. transportation, parking, etc)	1	2	3	4	5
c. Patient's limited access to transportation	1	2	3	4	5
d. Lack of primary care giver in patient's home	1	2	3	4	5
e. Inablility to communicate due to language barriers	1	2	3	4	5
f. Reluctance to use interpretor when discussing consent	1	2	3	4	5
g. Patient can't read consent form	1	2	3	4	5
h. Geographic barriers	1	2	3	4	5
i. Patient's insecurity with trial uncertainty	1	2	3	4	5
j. Information about current trials is not readily available to me	1	2	3	4	5
k. Time involved in offering trial is too great	1	2	3	4	5
l. Other_____	1	2	3	4	5

17. The following therapies are currently under laboratory or Phase I investigation, and may go on to Phase II and Phase III clinical trials. If these trials became available, in addition to your other recommended treatment would you consider entering the patient on the videotape who had 3 of 29 lymph nodes positive in any of the following trials:
(HAND PHYSICIAN NOTECARD 6)

Y N a. The use of estrogen along with tamoxifen to prevent hot flashes and heart disease

Y N b. The use of a Chinese herbal therapy sho-saiko-to, which has been used to treat cancers for centuries in that country

Y N c. A trial randomizing to tamoxifen alone, or tamoxifen plus monoclonal antibodies against breast cancer cells

Y N d. A trial of tamoxifen alone or tamoxifen with monoclonal antibody therapy to the HER-2/neu receptor

Y N e. A trial of standard chemotherapy alone or a vaccine-based chemotherapy to the Siacyl-TN antigen

Y N f. A trial of placebo vs. high-dose vitamin E and betacarotene

D. BACKGROUND

I would now like to get some information about your background and medical training.

1. What is your date of birth? MONTH ____ DAY ____ YEAR ____

2. Which of the following would you use to describe yourself? Are you:

   1 Board eligible in your specialty
   2 a board-certified specialist with no sub-specialty
   3 a board-certified specialist with a sub-specialty
   what is your sub-specialty?_____

We're interested in finding out some general characteristics of your caseload.

3. What was the location of your fellowship or most advanced training?

_____

4. At the site of this training, what percentage of patients were enrolled in clinical trials?

   a. <10% ____
   b. 11-50% ____
   c. 51-90% ____
   d. >90% ____

5. Approximately what proportion of your caseload is:

   a. female _____
   b. Caucasian (not including Hispanic or Portuguese) _____
   c. under 65 years _____
   d. 65-74 years _____
   e. 75-84 years _____
   f. older than 85 _____

   TOTAL 100

[NOTE: THE SUM OF C THROUGH F ABOVE SHOULD BE 100. CLARIFY IF IT IS NOT.]

6. a. How many outpatients do you see during an average week? ___

b. How many outpatients do you see with diagnosed breast cancer during an average week? ___

c. How many outpatients do you see for evaluation of possible cancer during an average week? ___

d. How many outpatients do you see for evaluation of possible breast cancer during an average week ? ___

e. How many times do you operate in an average week? ___

7. Do you give chemotherapy? 1. NO 2. YES

8. Do you provide radiation therapy? 1. NO 2. YES

9. In your primary practice, do you {does your institution} accept Medicare as a preferred provider?
1. NO 2. YES

10. What proportion of your caseload is Medicaid? _____%

11. Do you currently have hospital privileges?
1. NO 2. YES

12. What is your major hospital affiliation?

_____

13. Is this a

NO	YES	
_____	_____	private hospital
_____	_____	teaching hospital
_____	_____	community hospital
_____	_____	other type of hospital, please specify _____

This concludes our interview. Again, thank you for your assistance. We greatly appreciate your time and cooperation.

TIME INTERVIEW ENDED:_____

TOTAL TIME:____HOURS____MINUTES

INTERVIEWER's NOTES

1. Please rate how comfortable the respondent was during the interview.

Not at all comfortable.....Very comfortable

1 2 3 4 5

2. Please rate how cooperative the respondent was during the interview.

Not at all cooperative.....Very cooperative

1 2 3 4 5

3. Did the respondent have difficulty answering any questions?

1. No 2. Yes ----- which ones? _____

_____

4. Was anyone present during the interview?

1. No 2. Yes ----- who? _____

_____

5. Were there any unusual circumstances during the interview?

1. No 2. Yes ---- please explain:

_____

_____

6. Please check if the respondent :

_____ asked who the doctor is (i.e. their name or affiliation).

_____ made a positive comment about how realistic the videotapes are.

_____ asked if the actors were "real" or actors (R thought they were real).

_____ asked if the actors were "real" or actors (R thought they were actors).

_____ other: _____

_____

NOTECARD 1

From 1-5, how would you describe your style of presenting treatment or management recommendations?

1 = I would only offer the treatment I would perform myself

2 = I would strongly recommend the treatment I would perform myself

3 = I would strongly recommend my treatment choice

4 = I would recommend my treatment choice, but encourage patient to consider options

5 = I would allow patient to choose without a recommendation

NOTECARD 2

On the following scale, how would you describe your style of presenting treatment or management recommendations?

1 = I would offer patient all options

2 = I would offer options only if the patient requests them

3 = I would offer options, but emphasize my choice

4 = I would offer options, but would only perform my treatment choice

5 = I would not offer options

NOTECARD 3

When seeing a patient like the one you saw in the video, how important are the following when considering her appropriateness for a clinical trial?

1 = very important

2 = somewhat important

3 = neither important nor unimportant

4 = somewhat unimportant

5 = unimportant

NOTECARD 4

Based on your experience with your own patients, how likely do you think the patient in the videotape is to:

1 = not likely

2 = somewhat unlikely

3 = neither unlikely nor likely

4 = somewhat likely

5 = very likely

NOTECARD 5

In your practice, how frequently do you encounter the following barriers when you consider recommending a clinical trial?

1 = all of the time

2 = very often

3 = half of the time

4 = not very often

5 = never

NOTECARD 6

In addition to your other recommended treatment, would you consider entering the patient in the videotape with 3/29 lymph nodes positive in any of the following trials?

Y N a. The use of estrogen along with tamoxifen to prevent hot flashes and heart disease

Y N b. The use of a Chinese herbal therapy sho-saiko-to, which has been used to treat cancers for centuries in that country

Y N c. A trial randomizing to tamoxifen alone, or tamoxifen plus monoclonal antibodies against breast cancer cells

Y N d. A trial of tamoxifen alone or tamoxifen with monoclonal antibody therapy to the HER-2/neu receptor

Y N e. A trial of standard chemotherapy alone or a vaccine-based chemotherapy to the Sialyl-TN antigen

Y N f. A trial of placebo vs. high-dose vitamin E and betacarotene

APPENDIX 2

SELF-ADMINISTERED QUESTIONNAIRE

BREAST DISEASE

AND

DECISION MAKING:

Self-Administered Questionnaire

1. Among elderly patients, are the following conditions:

1 = More common at age 60-70 than at age 80+;
2 = More common at age 80+ than at age 60-70;
3 = Equally common at age 60-70 and age 80+?

a. breast cancer	1	2	3
b. breast cysts	1	2	3
c. FCD (fibrocystic disease)	1	2	3
d. fibroadenoma	1	2	3

2. Are the following conditions:

1 = More common in white patients than in black patients;
2 = More common in back patients than in white patients;
3 = Equally common in white patients and black patients?

a. breast cancer	1	2	3
b. breast cysts	1	2	3
c. FCD (fibrocystic disease)	1	2	3
d. fibroadenoma	1	2	3

3. Has a member of your family had any of the following?
(Please check yes or no for each)

	NO	YES
a. breast cancer	____	____
b. breast cysts	____	____
c. FCD (fibrocystic disease)	____	____
d. fibroadenoma	____	____

4. We want to know where you get any new information on emerging developments in the management o breast cancer. For each item, how important is this source in informing you about new developments in breast cancer management?

1 = never consult this source
2 = very unimportant source
3 = somewhat unimportant source
4 = somewhat important source
5 = very important source

a. Research presentations at professional medical meetings	1	2	3	4	5
b. The lay press (including newspapers, magazines, elevision, and radio)	1	2	3	4	5
c. Professional medical journals	1	2	3	4	5
d. CME courses	1	2	3	4	5
e. Other physicians (consultants)	1	2	3	4	5
f. NCI publications	1	2	3	4	5
g. FDA publications	1	2	3	4	5
h. Requests from patients	1	2	3	4	5

5. Please rate how much the following sources influence the way you practice medicine and treat patients with breast cancer. For each item, how influential is this source in informing you about new developments in breast cancer management?

1 = never consult this source
2 = very uninfluential source
3 = somewhat uninfluential source
4 = somewhat influential source
5 = very influential source

a. Research presentations at professional medical meetings	1	2	3	4	5
b. The lay press (including newspapers, magazines, television, and radio)	1	2	3	4	5
c. Professional medical journals	1	2	3	4	5
d. CME courses	1	2	3	4	5
e. Other physicians (consultants)	1	2	3	4	5
f. NCI publications	1	2	3	4	5
g. FDA publications	1	2	3	4	5
h. Requests from patients	1	2	3	4	5

6. The following questions ask for your opinion about different groups in the community for which you as a doctor provide services. **Please circle** the number corresponding to whether you strongly agree, somewhat agree, neither agree nor disagree, somewhat disagree or strongly disagree with each statement. Remember there are no right or wrong answers.

1 = Strongly agree
2 = Somewhat agree
3 = Neither agree nor disagree
4 = Somewhat disagree
5 = Strongly disagree

a.	Community organizations would function more smoothly if older persons were included in their governing boards.	1	2	3	4	5
b.	The older my friends get, the less respect they have for the privacy of other.	1	2	3	4	5
c.	Older people usually interfere with their adult children's childbearing practices.	1	2	3	4	5
d.	I would prefer to always live in an area where people my age predominate.	1	2	3	4	5
e.	I would always want to live in a neighborhood where there was a variety of age groups.	1	2	3	4	5

7. **Please circle** the number corresponding to whether you strongly agree, somewhat agree, neither agree nor disagree, somewhat disagree, or strongly disagree with each statement.

1 = Strongly agree
2 = Somewhat agree
3 = Neither agree nor disagree
4 = Somewhat disagree
5 = Strongly disagree

a.	Women should take care of running their homes and leave running the country to the men.	1	2	3	4	5
b.	Having a job means having a life of your own.	1	2	3	4	5
c.	A woman should have exactly the same job opportunities as a man.	1	2	3	4	5
d.	Men and women should be paid the same money if they do the same work.	1	2	3	4	5
e.	A women should realize that just as she is not suited for heavy physical work, there are also other jobs that she is not suited for, because of her mental and emotional nature.	1	2	3	4	5

8. The following are a series of statements about physicians' attitudes toward practice. For each item, how would you rank your agreement with this statement:

1 = strongly agree
2 = somewhat agree
3 = neither agree nor disagree
4 = somewhat disagree
5 = strongly disagree

1.	My enjoyment of the practice of medicine is substantially lessened because of the threat of lawsuits.	1	2	3	4	5
2.	The uncertainty of patient care often troubles me.	1	2	3	4	5
3.	If I do not make a diagnosis, I worry that the referring physician will stop sending patients to me.	1	2	3	4	5
4.	I rarely worry about being sued.	1	2	3	4	5
5.	I find the uncertainty involved in patient care disconcerting.	1	2	3	4	5
6.	The hardest thing to say to patients or their families is "I don't know."	1	2	3	4	5
7.	I almost never tell other physicians about diagnoses I have missed.	1	2	3	4	5
8.	When I have a patient who has sued another physician, I worry a lot.	1	2	3	4	5
9.	Uncertainty in patient care makes me uneasy.	1	2	3	4	5
10.	Trying to contain costs is the responsibility of every physician.	1	2	3	4	5
11.	When physicians are uncertain of diagnosis, they should share this information with their patients.	1	2	3	4	5
12.	There is currently too much emphases on costs of tests and procedures.	1	2	3	4	5

13.	If I shared all of my uncertainties with my patients, they would lose confidence in me.	1	2	3	4	5
14.	My choice of specialty was influenced by malpractice worries.	1	2	3	4	5
15.	Doctors are too busy to worry about the costs of tests and procedures.	1	2	3	4	5
16.	If I share my uncertainties with patients, I will increase the likelihood that I will be sued.	1	2	3	4	5
17.	Doctors need to take a more prominent role in limiting use of unnecessary tests.	1	2	3	4	5
18.	It is unfair to ask physicians to be cost-conscious and still keep the welfare of their patients foremost in their mind.	1	2	3	4	5
19.	I am afraid other physicians would doubt my ability if they knew about my patient care mistakes.	1	2	3	4	5
20.	I always share my uncertainty with patients.	1	2	3	4	5
21.	The cost of a test or medication is only important if the patient has to pay for it out-of-pocket.	1	2	3	4	5
22.	I refuse to perform certain procedures because of malpractice concerns.	1	2	3	4	5
23.	I never tell other physicians about patient care mistakes I have made.	1	2	3	4	5

9. The following are a series of statements which a person might use to describe himself. If you agree with a statement or decide that it does describe you, answer true, If you disagree with a statement or decide that it does not describe you, answer false.

	Please answer <u>each</u> of the questions true or false.	TRUE	FALSE
a.	I feel confident when directing the activities of others	1	2
b.	I would make a poor military leader.	1	2
c.	I would like to be a judge.	1	2
d.	I avoid positions of power over people.	1	2
e.	I try to control others rather than permit them to control me.	1	2
f.	I don't like to have the responsibility for directing the work of others.	1	2
g.	I would like to play a part in making laws.	1	2
h.	I have little interest in leading others.	1	2
i.	In an argument, I can usually win others over to my side.	1	2
j.	I feel uneasy when I have to tell people what to do.	1	2
k.	The ability to be a leader is very important to me.	1	2
l.	Most community leaders do a better job than I could possibly do.	1	2
m.	I am quite effective in getting others to agree with me.	1	2
n.	I am not very insistent in an argument.	1	2
o.	I would like to be an executive with power over other.	1	2
p.	I would not want to have a job enforcing the law.	1	2

The following questions concern choices you personally would make. When faced with a choice between alternative options, some people prefer one thing while others prefer the second. If you were faced with the following pairs of situations, each with a different probability of gaining money, which would you choose? For each pair of choices listed below, please circle the number of choices you wold prefer (1 or 2).

10. 1 90% probability of $2,000 and 10% probability of nothing

    2 100% probability of $1,800

11. 1 10% probability of $16,000 and 90% probability of nothing

    2 100% probability of $1,600

12. 1 50% probability of $5,000 and 50% probability of nothing

    2 100% probability of $2,500

13. One concern some physicians have these days is the treatment of malpractice suits. In you typical day to day work how much of a concern would you say this is for you in considering what tests to order? Please circle one number which best represents your level of concern.

No Concern									Most important Concern
1	2	3	4	5	6	7	8	9	10

14. And finally, what would you say is the medical specialty of the doctor in the videotapes?_____

==========

THANK YOU FOR YOUR TIME AND HELP.

APPENDIX 3

SCHEDULE FOR TRAINING OF INTERVIEWERS

BOSTON UNIVERSITY SCHOOL OF MEDICINE

BOSTON UNIVERSITY MEDICAL CENTER HOSPITAL

Section of General Internal Medicine

720 Harrison Avenue, Suite 1108
Boston, Massachusetts
02118-2334
TEL: 617 638-8030
FAX: 617 638-8026

Interviewer Training Session

The Role of Physicians Gender in Variation In Breast Cancer Care

Karen M. Freund MD MPH Principal Investigator
Boston University Medical Center Hospital

John B. McKinlay PhD Co-Principal Investigator
New England Research Institutes

December 4 - 6, 1995

Boston and Watertown, Mass.

Training Faculty

Karen M Freund MD MPH
Risa B Burns MD MPH
Renee Boss AB
Mark Moskowitz MD

Boston University Medical Center Hospital
720 Harrison Avenue, #1108
Boston, MA 02118

John B. McKinlay PhD
Linda Kasten MA
Dennis Cohen BA
Rita McNally BA

New England Research Institutes
9 Galen Street,
Watertown MA 02172

SCHEDULE

Monday, December 4, 1995
New England Research Institutes, Watertown

9:00 - 9:15	Introductions, Welcome. (Freund, McKinlay)
9:15 - 10:45	Lecture: The Diagnosis and Treatment of Breast Cancer, (Freund)
10:45 - 11:00	Break
11:00 - 12:00	Interviewing Skills, (Kasten, Cohen)
12:00 - 1:00	Lunch (provided)
1:00 - 2:30	Interviewing Skills, cont.
2:30 - 2:45	Break
2:45 - 5:00	Question-by-question review of interviewer-administered instrument. (Kasten, Cohen, McNally)
5:00	Adjourn for day. Interviewers to review questionnaires for next day session, study glossary of terms

Tuesday, December 5, 1995
NERI, Watertown MA

8:30 - 10:00	Review of interviewer-administered instrument, cont.
10:00 - 10:15	Break
10:15 - 12:00	Review of self-administered questionnaire
12:00 - 1:00	Lunch (provided)
1:00 - 2:00	Glossary of Medical terms. (Boss, Cohen).
2:00 - 3:30	Observation of Mock Interview.(Cohen, Kasten)
3:30 - 3:45	Break
3:45 - 4:30	Discussion of mock interview.
4:30	Adjourn, Interviewers to prepare for next day's practice interviews

Wednesday, December 6, 1995
Boston University Medical Center

Practice Interview Schedule

8:00 - 10:30	Boss - Vaughn
	Burns - Scheffield
10:30 - 10:45	Break
10:45 - 12:15	Boss - Scheffield
	Burns - Schreiner
12:15 - 1:30	lunch (on your own)
1:30 - 3:00	Boss - Schreiner
	Burns - Vaughn
2:45 - 3:00	Break
3:00 - 4:30	Review of performance of the practice interviews. (Boss, Burns, Freund, Cohen, Kasten, Moskowitz)
4:30 - 5:00	Wrap - up session. (Freund, Kasten, Cohen)

APPENDIX 4

INSTITUTIONAL REVIEW BOARD APPROVAL AND CONSENT FORM

BOSTON UNIVERSITY
MEDICAL CENTER
The University Hospital

88 East Newton Street
Boston, Massachusetts 02118-2393
617 638-
617 638- fax

Karen Freund, M.D.
General Internal Medicine
P 1108

December 14, 1994

RE: Protocol E3455/94

Dear Doctor Freund:

The Status Report for your research project, entitled The Role of Physician Gender in Variation in Breast Cancer Care, referenced above, was reviewed by the Institutional Review Board for Human ReseARch.

I am pleased to inform you that the continuation of this project has been approved. Approval is valid for a period of one year.

Enclosed you will find a validated consent form which shows the date through which it will be in effect. It is mandatory that you remove from your files any and all non-valid forms and use the enclosed as an original for the purpose of reproduction.

Please remember that all signed consent form documents must be retained for a period of three years past the completion of this research.

If you have any questions regarding this, please do not hesitate to contact me at extension 7207.

Sincerely,

Linda L Frattura

Linda L. Frattura
Administrative
Coordinator
I.R.B.

Boston University
School of Medicine

BOSTON UNIVERSITY
MEDICAL CENTER
The University Hospital

Section of General
Internal Medicine
720 Harrison Avenue, Suite 1105
Boston, Massachusetts 02118-2334
TEL: 617 638-8030
FAX: 617 638-8026

PHYSICIAN DECISIONS IN BREAST CANCER CARE

INFORMED CONSENT

Recent work on physician preference suggests that while this process is guided by medical criteria, other considerations also influence physicians. The purpose of this research study is to identify which factors are operative in physician's decisions and what implications arise as a result.

Physicians asked to participate in this study are randomly selected from mailing lists developed from the membership of professional societies and other sources. At this time, we would like to encourage your cooperation in this research endeavor.

Your involvement in this study is two-fold. First, we will present you with two videotaped simulated doctor-patient encounters, which we would like you to consider and render diagnostic and treatment recommendations. Each evaluation should take no more than 5-7 minutes to view. Second, a senior member of our interviewing staff will conduct a brief interview with you so that we might learn a little about you personally and professionally. This interview should take no more than 50 minutes to complete. The total of your time involvement will be approximately one hour. At any time you may refuse to answer questions or withdraw from the study.

We recognize that most clinicians are extremely busy. As such, we will make special efforts to carry out the data collection at times and in places which are convenient to each participating physician.

All precautionary measures will be taken to ensure subject confidentiality and privacy. All data (from interviews and simulation evaluations) will be safely secured in locked cabinets, and access to this data will be restricted to the Principal and Co-Principal investigators. All data will be published in aggregate form only.

There are no foreseeable risks or discomforts associated with your participation in this research. It is hoped that, as a result of this study, we will be able to understand more fully the factors taken into account by physicians in reaching diagnostic and therapeutic decisions. With the knowledge, we hope that future efforts can be directed at rationalizing the clinical decision-making process. You also will be paid $100 at the completion of the interview.

IRB 12/14/94

Research Staff Initials_____ Physician Initials_____

Date_____ Date_____

Representatives from the U.S. Army Medical Research, Development, Acquisition and Logistics Command are eligible to inspect the records of this research as a part of their responsibilities to protect human subjects in research.

If you have any questions regarding the research or your participation in it, either now or at any time in the future, please feel free to ask them. The research team, particularly Karen Freund, M.D., who may be reached at 638-8030, will be happy to answer any questions you may have. You may obtain further information about your rights as a research subject by calling the Coordinator of the Institutional Review Board for Human Research of Boston University Medical Center at 638-7266. If any problems arise as a result of your participation in this research, including research-related injuries, please call the principal investigator, Karen Freund, M.D., at 638-8030 immediately.

You are not obligated to participate in this research. If you choose not to participate, your present and/or future standing in the medical community will not be affected in any way. Also, if you participate, you may withdraw your consent and discontinue participation at any time without affecting you in any manner.

It is hoped that you will agree to participate in this research, by signing this informed consent form in the space provided. Your help is vital to the success of this study. If you have any questions concerning this study, please feel free to contact one of the following:

Karen M. Freund, M.D., M.P.H.
Principal Investigator
(617) 638-8030

John B. McKinlay, Ph.D.
Co-Principal Investigator
(617) 923-7747

SUBJECT'S STATEMENT OF CONSENT

You are authorized all necessary medical care for injury or disease which is the proximate result of your participation in this research. Other than medical care that may be provided and the $100 professional fee, you will not receive any compensation for your participation in this research study; however, you understand that this is not a waiver or release of your legal rights.

I have read the above description of this research study, and I understand it. I have been informed of the risks and benefits involved, and all of my questions have been answered to my satisfaction. Furthermore, I have been assured that any future questions I may have will also be answered by a member of the research team. I understand that I will receive a copy of this form.

IRB 12/14/94

Research Staff Initials_____ Physician Initials_____

Date_____ Date_____

I understand that I am free to withdraw this consent and discontinue participation in this research study at any time without prejudice.

I voluntarily consent to my participation in the described research study.

Signature of Physician	Signature of Research Staff
Printed Name of Physician	Printed Name of Research Staff
Address	
	Date

Valid for use through 12/31/95
Per IRB LLF 12/14/94

PHYSICIAN DECISIONS IN BREAST CANCER CARE

INFORMED CONSENT

Recent work on physician preference suggests that while this process is guided by medical criteria, other considerations also influence physicians. The purpose of this research study is to identify which factors are operative in physician's decisions and what implications arise as a result.

Physicians asked to participate in this study are randomly selected from mailing lists developed from the membership of professional societies and other sources. At this time, we would like to encourage your cooperation in this research endeavor.

Your involvement in this study is two-fold. First, we will present you with two videotaped simulated doctor-patient encounters, which we would like you to consider and render diagnostic and treatment recommendations. Each evaluation should take no more than 5-7 minutes to view. Second, a senior member of our interviewing staff will conduct a brief interview with you so that we might learn a little about you personally and professionally. This interview should take no more than 50 minutes to complete. The total of your time involvement will be approximately one hour. At any time you may refuse to answer questions or withdraw from the study.

We recognize that most clinicians are extremely busy. As such, we will make special efforts to carry out the data collection at times and in places which are convenient to each participating physician.

All precautionary measures will be taken to ensure subject confidentiality and privacy. All data (from interviews and simulation evaluations) will be safely secured in locked cabinets, and access to this data will be restricted to the Principal and Co-Principal investigators. All data will be published in aggregate form only.

There are no foreseeable risks or discomforts associated with your participation in this research. It is hoped that, as a result of this study, we will be able to understand more fully the factors taken into account by physicians in reaching diagnostic and therapeutic decisions. With the knowledge, we hope that future efforts can be directed at rationalizing the clinical decision-making process. You also will be paid $100 at the completion of the interview.

IRB 12/14/94

Research Staff Initials_____ Physician Initials_____

Date_____ Date_____